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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/075,375	05/07/1998	HARRY Y. YAMAMOTO	CGNE119-2US	3584

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CALGENE LLC
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EXAMINER

NELSON, AMY J

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/12/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/075,375

Applicant(s)

YAMAMOTO ET AL.

Examiner

Amy Nelson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The finality of the Official action mailed 7/27/01 is withdrawn in view of the following new grounds of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-5 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward a DNA sequence encoding plant violaxanthin de-epoxidase, as well as plants and plant cells transformed with said DNA sequence, and methods of plant transformation with said DNA sequence. Applicant describes the nucleic acid sequences of SEQ ID NO:1 (from *Latuca*), SEQ ID NO:3 (from *Nicotiana*) and SEQ ID NO:5 (from *Arabidopsis*), and the encoded amino acid sequences of SEQ ID NO:2, SEQ ID NO:4 and SEQ ID NO:6, respectively. The nucleic acid sequences are 1981 nucleotides, 1589 nucleotides, and 1555 nucleotides in length, whereas the amino sequences are each 1412 amino

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acids in length. The nucleic acid sequences are not of sufficient length to encode the amino acid sequences. Hence, it does not appear that Applicant has described a single full length DNA encoding violaxanthin, and it is not clear from the instant specification that the Applicant was in possession of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

4. Claims 3-5 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims an isolated DNA encoding plant violaxanthin de-epoxidase (VDE), as well as a plant or plant cell comprising said DNA. Applicant also claims a method of modifying violaxanthin de-epoxidase levels in a host cell or a plant.

Applicant teaches purification of VDE from lettuce, partial amino acid sequencing, and PCR amplification of a cDNA using oligonucleotides based on the amino acid sequence (Example 1), and teaches expression of the cDNA in *E. coli* (Example 2). Applicant also teaches

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Western analysis of various plant species (Example 3), and Applicant teaches antisense expression of a tobacco cDNA operably linked to the CaMV 35S promoter in transgenic tobacco plants, and teaches that the plants have reduced levels of expression of zeaxanthin (Example 4).

Although Applicant asserts that the isolated lettuce cDNA comprises an open reading frame, Applicant has not defined the open reading frame. Moreover, Applicant has provided sequences in the sequence listing for a tobacco and an *Arabidopsis* nucleic acid, however Applicant has not taught how the sequences were isolated, nor if the sequences comprise a complete open reading frame. The disclosed nucleic acid sequences are 1981, 1589 and 1555 nucleotides in length. The sequence listing comprises the amino acid sequences of SEQ ID NO:2, 4, and 6, which are all 1412 amino acids in length. The disclosed nucleic acids are not of sufficient length to encode the disclosed amino acid sequences, and hence do not appear to be full length. According to the Brief Description of Drawings, these are the encoded VDE proteins. However, the specification also states that the encoded protein is 473 amino acids (specification, p. 18). Applicant has not clearly defined the size of the full length polypeptide, nor the sequence of a full length cDNA that encodes the polypeptide. Moreover, Applicant has taught expression of the tobacco cDNA in tobacco (Example 4), but Applicant has not taught the region of the disclosed gene which was operably linked to the CaMV 35S promoter. In the absence of appropriate guidance, undue trial and error experimentation would be required to practice the claimed invention. In the event that Applicant is able to point to guidance in the specification that

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does enable the claimed invention, the scope of enablement will be limited to the teachings and guidance provided in the specification.

Further, it is noted that Applicant has only taught transformation of bacterial and plant host cells. Applicant has not taught transformation of mammalian or other host cells, and it is not clear that VDE levels could be successfully modified in other host cells by the claimed methods.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3-5, and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 3, the limitation "and wherein said violaxanthin de-epoxidase protein is recognized by a polyclonal antibody prepared against a peptide comprising the amino acid sequence VDALKTCACLLK (SEQ ID NO:7)" is a meaningless limitation as it is clear that any plant VDE would be recognized by such a polyclonal antibody. Hence, the limitation does not further limit the claim, and should be deleted.

Claim 11 is improperly dependent on Claims 4, 5 and 9. Claims 4 and 5 are directed to a method of modifying VDE levels in a host cell, and not to a method of producing a plant, plant

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cell or plant part. Claim 9 is directed to a method of modifying zeaxanthin levels and not to a method of producing a plant, plant cell or plant part.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM.

The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.



**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

Amy J. Nelson, Ph.D.

March 11, 2002